

### **DETAILED ACTION**

The amendment filed 2/19/2008 has been received, entered and carefully considered.

The following information provided in the amendment affects the instant application:

1. Claims 1-13 have been canceled.
2. Claims 14, 15, 22, 26 and 27 have been amended.
3. Remarks drawn to rejections under 35 USC 112, first and second paragraphs, double patenting and 103.

Claims 14-28 are pending in the case.

#### ***Claim Objections***

The objection to Claim 26 because of the following informalities: Claim 26 recites a first structural formula, which is labeled as (I) and (II) and further recites another structural formula which is labeled (II), is being maintained. Applicants have not corrected the formula numbering.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of Claims 14-23, 25 and 27-28 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising the carbohydrate of formula I, does not reasonably provide enablement for a composition comprising the carbohydrate of formula I and further carbohydrates which are different, active agents(s),

ingredients, auxiliaries, moisturizing agents, thickening agents, flavoring agents sweetening agents and carriers, method of treatment and prevention of immunomodulation, immunosuppression and infections, is being maintained for reasons of record.

Applicants have traversed the enablement rejection made of record earlier by arguing that the amended claims refer to the definitions of sialic acid derivatives as the acetyl derivatives. Based on this and the level of one of skill in the art the specification is enabling.

Applicants' arguments are not found to be persuasive. Just defining the instant carbohydrates as O-acyl derivatives and the mechanism of operation without representative examples does not enable the methods of treatment and prevention as instantly claimed. The rejection is being maintained for claims 14-23, 25 and 27-28.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of Claims 14-28 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is being maintained for reasons of record.

The term "several" recited in claims 14 and 25 is a relative term which renders these and all other claims in which the said term is recited indefinite. The term "several" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention is being maintained. The claims still recite the term several.

The rejection of Claim 14 is being maintained for reasons of record. Applicants have not specifically addressed claim 14 but have provided an explanation regarding the meaning of V and the carrier with reference to claim 15. According to the claim 14 V represents a carbohydrate residue or a carrier T. According to applicants remarks (page 9, second paragraph) the carrier can be a further carbohydrate. If this is the case then is T different from this carbohydrate? If this is the case then the claim has a broad (carrier) and a narrow (carbohydrate) recitation. Moreover from the claim recitation and applicants' explanation it appears that formula (II) is attached to formula (I) via a carrier T wherein n totals to 50. Is this what applicants intend? Further clarification is still needed.

The rejection of Claim 15(i) and 27 (i) for clarification if the glycol residue or N-glycosyl residue is intended, has been overcome in view of applicants clarification.

Regarding the rejection of claim 17 for the recitation of the terms, head group(s), applicants have stated that the terms are well known to the skilled artisan and that the terms terminal group or end group is another term for such a group. The terms end group or terminal group are seen to convey clearly what is intended compared with head group. Reciting head group does not clearly convey which end of the structure is the head and which is the tail. Applicants are requested to use the terms end group in the said claim.

Regarding the rejection of Claim 20 for recitation of the terms "at least 1mg of formula I per kg of body weight", applicants have argued that the upper limit is not known and it depends on the body weight and other factors. If this is the case then the claim should recite the amount with respect to the body weight or other factors that may be important. Leaving the upper limit open conveys that it could be any amount, which is indefinite.

The rejection of Claim 22 has been overcome by amendment.

The rejection of claim 25 is being maintained for reasons of record. Regarding the rejection of Claim 25 applicants argue that the composition claimed may contain other known active compounds and/or usual ingredients. This is not found to be persuasive. The claim does not define what the said agents and usual ingredients are. A definition for the said terms is not seen in the specification either.

Claims that depend from a rejected base claim that is unclear/indefinite are also rendered unclear/indefinite and are rejected for the same reasons.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of Claim 10 provisionally on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3 and 7 of copending Application No.

Art Unit: 1623

10/148,193('193 application) is being maintained for reasons of record. Applicants have requested that the filing of a Terminal Disclaimer be held in abeyance till allowable subject matter is indicated in one of the applications. The rejection will be dropped after the filing and approval of the Terminal Disclaimer.

The rejection of Claim 10 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6 and 9-10 of U.S. Patent No. 6,576,251 ('251 patent) has been rendered moot by cancellation of claim 10.

Claim 24 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6 and 9-10 of U.S. Patent No. 6,576,251 ('251 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Applicants arguments for the rejection of claim 10 is seen as applicable for instant claim 24. Applicants have traversed the rejection arguing that the '251 patent deals with carbohydrates mixtures wherein the carbohydrates have different chain lengths and furthermore, fucose has to be present. Fucose is not mentioned in the instant application and hence the rejection should be withdrawn. This is not found to be persuasive. The carbohydrates of the instant invention and those of the '251 patent have chain lengths that overlap. Moreover, claims 1, 6 and 9 of the '251 patent do not require the presence of fucose. The rejection is being maintained for instant claim 24.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of Claims 14-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilbert et al (WO 00/46379; document cited in IDS of 30 July 2004) is being maintained for reasons of record.

Applicants have traversed the rejection by arguing that:

1. The main focus of the Gilbert reference is synthesis and not the pharmacological activities of the compounds.
2. Gilbert teaches that his compounds can be used as antigens and therapeutic agents. This teaching is extremely broad and can mean any variety of conditions. No specific therapeutic use is disclosed by Gilbert.

Applicants' arguments have been considered but are not found to be persuasive.

Applicants' methods of treatment as instantly claimed are also broad and can include a variety of conditions and not limited to treat any specific conditions. Gilbert teaches that his compounds are useful for treating a variety of conditions. In addition to this he suggests the use of the compounds as immunogens. Even thought the use as immunogen is for making monoclonal or polyclonal antibodies, at page 43, lines 14-16, Gilbert discloses that animals can be immunized (immunomodulation or suppression) with a preparation containing the oligosaccharides of his invention. This is a suggestion regarding the method of use for the oligosaccharides as instantly claimed.

### ***Conclusion***

Claims 14-28 are rejected

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GK

/Shaojia Anna Jiang, Ph.D./

Supervisory Patent Examiner, Art Unit 1623